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<p>(21) International Application Number: PCT/US92/11311 (22) International Filing Date: 30 December 1992 (30.12.92) (30) Priority data: 3/113712 U 30 December 1991 (30.12.91) JP (71) Applicant (for all designated States except US): SCIMED LIFE SYSTEMS, INC. [US/US]; 6655 Wedgwood, Maple Grove, MN 55369-7503 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): IRIE, Toshiyuki [JP/JP]; A203 867-1 Ohaza Kitano, Tokorozawa, Saitama (JP). FRUI, Shigeru [JP/JP]; 2-308 2 Namiki 2-chome, Tokorozawa, Saitama (JP).</p>		<p>(74) Agent: AUBUCHON, F., David; William, Brinks, Olds, Hofer, Gilson &amp; Lione, NBC Tower, Suite 3600, 455 North Cityfront Plaza Drive, Chicago, IL 60611 (US). (81) Designated States: CA, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). <b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: THROMBOSIS FILTER</p> <p>(57) Abstract</p> <p>A thrombosis filter (I, II) that has an improved filtering function and can be securely anchored at a desired location and be removed through an endovenous route even after the growth of neointima. The thrombosis filter (I, II) of this invention includes a first and a second filtering and holding unit, each unit including a coupling mechanism (41, 42) at its outer extremity in the form of a hook, and a plurality of resilient struts (31, 32) which radiate from a central hub (51, 52) and lie on the surfaces of cones. The units are interconnected by a core shaft (1) which consists of a compression spring and a pair of core wires.</p> <div data-bbox="909 1134 1347 1827"> </div>		

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THROMBOSIS FILTERBACKGROUND OF THE INVENTION

The present invention relates to thrombosis filters.

5 To be more specific, it is about removable thrombosis filters which can be securely fixed at a selected location in the vascular system for trapping blood clots, and removed when desired such as when no longer required.

10 In recent years, pulmonary embolism has become an increasingly common medical emergency. Pulmonary embolisms may be caused by venous thrombosis that in turn may be caused by blood flow retention, venous intimal damage or coagulation abnormalities. Emergency or prophylactic treatments for these conditions include anticoagulant therapy, thrombolytic  
15 therapy, thrombectomy and inferior vena cava blocking procedures.

Among these therapeutic options, when an inferior vena cava blocking procedure is selected, one option is to perform a laparotomy under general anesthesia during which the  
20 inferior vena cava is ligated, sutured and shortened, or clipped. Another option is to intravenously insert a thrombosis filter into the inferior vena cava under local anesthesia. A laparotomy however, requires general anesthesia and is susceptible to thrombosis formation due to the  
25 discontinuation of anticoagulant therapy prior to surgery. For these reasons, percutaneous filter insertion is now more widely employed since it requires only local anesthesia.

Blood is returned to the heart from the lower part of the human body through the inferior vena cava and from the  
30 upper part of the body through the superior vena cava. The neck vein, known as the jugular vein, leads to the superior vena cava which is a vein that enters the upper part of the heart. A percutaneously inserted catheter that extends  
35 through the jugular vein and the superior vena cava and then into the heart can be manipulated to exit the heart through the mouth of the inferior vena cava into the heart. The inferior vena cava, a vein that enters the lower part of the

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heart, can also be accessed through the patients femoral vein. Thus, the inferior vena cava can be reached through two endovenous routes, both of which are available percutaneously.

A currently used percutaneous filter is shown in Figure 9. The filter has anchors, 43, at the end of six struts, 81, with a head or central hub or fixation part, 5. One example of how this filter is used is to lead the filter within a capsule with the head of the filter introduced first if using the transfemoral vein approach or with the tail of it introduced first if using the transjugular vein approach. This type of filter possesses hooks at the end of the struts that impinge the inner wall of the blood vessel in order to ensure its firm fixation at the time of insertion. It is released from the capsule and expands within the inferior vena cava where it function as thrombosis filter.

Filters of the type shown in Figure 9 perform the desired filtering function, requiring only local anesthesia for insertion. This has contributed to the high usage of the filter. A filter of the type shown in Figure 9 is disclosed in U.S. Patent No. 4,817,600. Approximately two to three weeks after insertion of this type of filter, neointima grows around the filter and its anchors to the inner wall of the blood vessel, which becomes an obstacle to the removal of the filter after its function has been fulfilled. Furthermore, this filter was not designed or intended to be removed. Since the need for a thrombosis filter, in many patients, is temporary, it may be desirable to remove the filter when it is no longer needed. In the prior art devices, such removal can be preformed surgically which exposes the patient to the usual risk and trauma associated with surgery. Thus there is a need for a thrombosis filter that can be removed without surgery.

The subject invention fulfills the need of a medical filter which can be non-surgically removed even after neointima has developed. As a result of this invention, a medical filter has been developed which includes insertion and removal accessories that enable the goal to be achieved. The filter of this invention includes a filtering portion that is

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permeable to the blood flow but which will filter out emboli and thrombus and will also hold the filter firmly in a selected location and permit removal through an endovenous route. The filtering and holding device of this medical filter includes two filter units that face each other and do not have hooks that impinge the inner wall of the blood vessel, in the same manner as the prior art filters, in order to anchor the device in the blood vessel.

The objective of this invention, therefore, is to provide thrombosis filters with a favorable filtering function which can be securely anchored at a desired location and be removed through an endovenous route even after the growth of neointima.

#### SUMMARY OF THE INVENTION

The above-mentioned objective is achieved by a thrombosis filter which is characterized by the following structure. The thrombosis filter of this invention includes a first and a second filtering and holding unit each unit including a coupling mechanism in the form of a hook. Each unit has a plurality of resilient struts which radiate from a central hub and lies on the surface of a cone. The units are interconnected by a core shaft which consists of a compression spring and a pair of core wires. The term compression spring means a spring that will draw the filtering and holding units toward each other to thereby minimize the overall longitudinal length of the filter. Inside the core shaft, there are core wires that are anchored in the units and have free ends which extend from their anchored ends toward the other unit. The struts are resilient and their free ends bear against the inner wall of the vein. However, the free ends do not include anchoring hooks, of the type disclosed in the prior art, that impinge the wall of the vein as does the above discussed prior art filter. The anchoring of the filter, of this invention, is accomplished by orientating the two filter units in opposite directions. The force from the compression springs pulls the hubs from the two units toward each other, which

tends to open the struts of both units thus forcing their free ends into the wall of the vein and holding the filter in its selected location. More specifically, the core shaft of the upper unit (as seen in Figure 1) consists of multiple struts which spread radially in an expansive direction while the core shaft of the lower unit consists of multiple struts which spread radially. The struts from the first and second units cross each other between their hubs and free ends, which when considering the conical surfaces that the struts lie upon, defines a V-shaped circular filtering groove. This V-shaped circular filtering groove is permeable to the flow of blood and performs an improved filtering function.

Although materials of the present thrombosis filters are not particularly restricted, it is desirable to use a flexible material that will return to its original shape after being deformed such as identity elastic alloy wire, high elastic alloy wire such as stainless steel, tungsten, platinum, piano wire, shape memory alloy wire, super elastic metal wire and chromium alloy. It is important that the coupling mechanisms in the form of hooks and the cord be constructed of material such a tungsten, platinum or gold that can be seen on a fluoroscope, to aid in the process of securing the coupling mechanisms.

Multiple number of struts or thrombosis filtering wires used for the present invention are divided into two units and are placed and anchored around their corresponding central hub at regular intervals to the extent possible. The struts of each unit lie on the surface of a cone with an anchoring part at the apex. The anchoring part is connected to and a part of the central hub.

Inside the compression spring, which constitutes the core shaft, a core wire extends from each of the filter units and function to reinforce the compression spring.

The angle between the radially spread struts and the core shaft can be optional, although it is preferable to maintain this angle within the range of 70 to 80 degrees.

The thickness of the wire constituting a strut is preferably 0.05 to 0.2 mm in diameter.

The ideal outside diameter of the compression spring is 0.5 to 2 mm in diameter, but there is no particular restriction to it. This diameter can of course be determined by the particular use intended for the filter.

As for the size of the thrombosis filters, there is no particular restriction. The size can be changed at one's discretion depending on the site of its application.

The present invention enables thrombosis filtering through multiple struts which spread radially. As a result the filtering and holding device is flexible in its radial dimension and can be compressed or collapsed radially for insertion, travel and removal. Since the struts do not have hooks for impinging the inner wall of the blood vessel, even when the struts are covered by neointima, they can be easily removed by pulling them towards the head or central hub. The compression spring, which serves as the core shaft, provides a core shaft that is flexible and facilitates maneuvering the filter units into the recovery tubes for removal. The compression spring allows relative movement of the units along the filter's longitudinal axis.

The core wires within the compression spring function to maintain the core shaft along a central axis extending between the two filter units as well as to achieve a desired flexibility of the compression spring.

The coupling mechanism, in the form of a hook element provided at the head of each filter unit, functions to connect the unit to mechanism that can be manipulated through an endovenous route at the time of removal.

As for the structure of the filter units facing each other, this arrangement serves to stabilize and anchor the filter inside the blood vessel and to prevent unfavorable phenomenon such as the displacement of the filter inside the vessels.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view showing the thrombosis filter of this invention.

5 Figure 2 is a perspective view showing a strut of the thrombosis filter of this invention.

Figure 3 is an top view of filter unit I of the thrombosis filter of this invention.

10 Figure 4 is a cross-sectional view illustrating a step in the method for removing the thrombosis filter of this invention from the patient.

Figure 5 is a cross-sectional view illustrating a step in the method for removing the thrombosis filter of this invention from the patient.

15 Figure 6 is a cross-sectional view illustrating a step in the method for removing the thrombosis filter of this invention from the patient.

Figure 7 is a cross-sectional view illustrating a step in the method for removing the thrombosis filter of this invention from the patient.

20 Figure 8 is a cross-section view of the head portion of the thrombosis filter of this invention taken along line 8-8 of Figure 1.

25 Figure 9 is a perspective view of a conventional prior art thrombosis filter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The following is a discussion of how the present invention can be applied to a particular embodiment. This, however, does not mean that the application of the present invention is limited only to the following use.

30 Figure 1 is a perspective view, of the filtering and holding device of the preferred embodiment of the present invention. The filter is fabricated mainly from stainless steel wires. The wire is 0.05 to 0.2 mm in diameter. The filter consists of twin units, I and II, that are spaced from each other along the filtering and holding device's



longitudinal axis and which face each other and are connected by the compression spring 1.

The filter unit I includes the following structure. The upper end of core wire 21, as viewed in Figure 1, extends downwardly from hook 41. Struts 31 also extend downwardly from hook 41 and spread radially in an expansive direction, centering around the core wire 21. The upper ends of struts 31 are fixed in the central hub or fixation part 51.

Filter unit II has the following structure. As viewed in Figure 1, the core wire 22 and struts 32 extends upwardly from hook 42. Struts 32 spread radially at an angle to the filtering and holding device's longitudinal axis in an expansive direction, centering around the core wire 22. The struts 32 are anchored at, their lower end in central hub or fixation part 52.

The free ends of the struts for both units I and II are thus spring biased outwardly and can be forced inwardly to decrease the diameter of the filtering and holding device when it is located in the insertion and removal tubes.

As shall be discussed in greater detail, a welding or binder material is normally used for brazing the ends of the hooks 41 and 42 the core wires 21 and 22 the struts 31 and 32 and the ends of spring 1 to the central hub or fixation parts 51 and 52.

The filter units I and II are spaced from each other along the filtering and holding device's longitudinal axis such that struts 31 and 32 crossed each other at about their mid points. Hooks 41 and 42 are constructed of tungsten or stainless steel wires that have been bent into the shape shown in Figure 1.

First ends of core wires 21 and 22 are connected to the central hub or fixation parts 51 and 52 along with the straight ends of hooks 41 and 42. The core wires 21 and 22 extend through the lumen formed by compression spring 1 and function as a core shaft that enhances the flexibility of compression spring 1. The other ends of core wires 21 and 22 are free.

Figure 2 is a diagonal view of a strut 31 that includes a head 33. Strut 32 is identical to strut 33 and thus is not illustrated in an isolated view. The heads 33 of struts 31 and 32 become a part of the core shaft by being anchored in central hub or fixation parts 51 and 52.

Figure 3 is a top view of filter unit I. As can be seen in this view, struts 31 emanate from the central core shaft and spread outwardly from this center in equal amounts into the surrounding area. Although six struts 31 in each filter unit have been found to be optimum, this number can be varied within the range of three to ten.

Figure 8 includes two enlarged cross-sectional views taken through the central hub or fixation part 51. A tube 53 is used to form the central hub or fixation part 51 of the thrombosis filter. The straight end of hook 41, first end of core wire 21 and the heads 33 of struts 31 are all inserted into the tube 53. The ends of spring 1 could also be inserted into the tube 53 and bonded to the tube 53 or the ends could be fixed to the tube by welding or adhesive. A bonding material 54 is then introduced, while in a pliable stage, into tube 53 such that the bonding material 54 fills all the voids between the ends of the hook 41, core wire 21 and heads 33 within tube 53. When the pliable material 54 hardens the ends of the hook 41, core wire 21 and the heads 33 are all fixed in the central hub or fixation part 51. The tube 53 could remain as a permanent part of central hub or fixation part 51 or it could be removed.

It should be noted that the compression spring 1, hooks 41 and 42, core wires 21 and 22 and the struts 31 and 32 can all be fabricated from the same material or each of these parts could be fabricated from different material that will provide the desired characteristics for the particular part.

The following is an explanation of how this embodiment of the thrombosis filter is used. The thrombosis filter is dimensioned such that it can be stored in the distal end of a thin tube (2 to 3 mm in diameter). This insertion tube is percutaneously inserted into the patient and follows

an endovenous route into the patient's inferior vena cava. This procedure is performed under local anesthesia. When the distal end of this tube reaches the target site, the filtering and holding device stored inside the tube is caused to exit the distal end of the tube where it become implanted in the patient's inferior vena cava. A pusher rod is extended through the insertion tube and is maneuverable from the proximate end of the insertion tube for expelling the filtering and holding device out the distal end of the insertion tube. It should be noted that the insertion procedure can be monitored on a fluoroscope.

The filtering and holding device after being released from the tube into the patient's inferior vena cava, through the above described procedure, is in the form as shown in figure 1. Within several week after the filtering and holding device has been implanted in the inferior vena cava, the struts 31 and 32, which are in contact with the inferior vena cava become covered by neointima.

When it becomes necessary or desirable to remove the filtering and holding device, the following procedure is followed. The term "medical filter" as used to describe and claim this embodiment includes in addition to the filtering and holding device the above mentioned insertion tube and the recovery hardware necessary to remove the filter. A recovery device is provided that can be inserted percutaneously and threaded through the endovenous route to the filtering and holding device. The recovery device includes a first tube 64, a second tube or sheath 61, a third tube 63 and a recovery tube or sheath 62.

Referring to figure 4, a doubled over cord 71 inserted through the proximal end of the first tube 64 such that the cord emerges at the distal end of the tube 64 and functions as a coupling mechanism in the form of a loop. The tube 64 then is passed through the second tube or sheath 61 which has been percutaneously inserted into the patient via the femoral vein such that its distal end is in the inferior vena cava of the patient adjacent the filtering and holding

device. The tube 64 is advanced, through tube or sheath 61, to the filtering and holding device. The tube 64, that has the loop formed in cord 71 emerging from its distal end, is manipulated such that the coupling mechanism in the form of a loop is grasp by the complementary coupling mechanism in the form of a hook 41.

In the same manner, a doubled over cord 72 is passed through third tube 63 such that a loop that functions as a coupling mechanism emerges from the distal end of the tube. Third tube 63 is threaded through a recovery tube or sheath 62 which was percutaneously inserted through the right internal jugular vein such that its distal end is in the patients inferior vena cava. The third tube 63 is manipulated such that the coupling mechanism in the form of a loop is grasped by the complementary coupling mechanism in the form of a hook 42. After cord 64 is connected to hook 41 and cord 72 is connected to hook 42 the cords 64 and 72 are simultaneously pulled in opposite directions, causing units I and II to move away from each other. The compression spring 1 expands to permit this relative movement of units I and II. A tension is maintained on the cords 64 and 72 to insure that the connection between the cords 64 and 72 and the hooks 41 and 42 is maintained.

Cords 64 and 72 are made of or include radiopaque material such as stainless steel so the at the coupling of the loops with hooks 41 and 42 can be monitored of a scope.

The relative movement of units I and II has resulted in a corresponding movement of the struts 31 and 32 relative to the vessel wall and the filters have been freed from the neointima.

The next step in the process of removing the filtering and holding device from the patient is illustrated in Figure 5. The cord 71 is pulled in its proximal direction to thus pull the filter unit 1 into tube or sheath 61 for temporary storage. Then tube 64 is advanced further through tube or sheath 61 to the point where its distal end is

adjacent the ends of struts 32 that are secured in the fixation member 51 of unit II.

As can be best seen in Figure 6, the next step in the removal procedure is to advance tube or sheath 62, in the direction toward its distal end, such that unit II and the distal end of tube or sheath 61 in which is stored unit I, are received within tube or sheath 62.

The entire filtering and holding device is now stored in recovery tube or sheath 62. By pulling one strand of cord 71, from its proximal end, cord 71 is released from hook 41 and can be removed from the patient. The second tube or sheath 61 can then be removed from the patient, and as shown in Figure 7, and the entire filtering and holding device is now stored in recovery tube or sheath 62.

The final step in the process for removing the filtering and holding device from its resting place in the patient's inferior vena cava is to pull out the recovery tube or sheath 62.

When the filters used for the present invention are employed in vessels, in order to prevent the adhesion of thrombosis it is preferable to coat the filters with antithrombotic agents (such as heparin, urokinase and antithrombotic material including hydroxy methacrylate-styrene copolymer).

As a result of the thrombosis filters units I and II being connected by a compression spring with the struts 31 and 32 extending in opposite directions, fixation of the filtering and holding device at a selected location is accomplished upon release of the filter from the tube. In addition, the arrangement of the struts 31 and 32 extending in opposite directions and crossing provides a very effective thrombus filter. Moreover, the thrombus filter of this invention can be removed when the patient no longer has a need for it.

It is claimed,

1. A medical filter adapted to be percutaneously implanted in and removed from a blood vessel of a patient through the endovenous route via a tube, said blood vessel having a flow of blood therethrough and possible clots and an inner wall, said medical filter comprising:  
a filtering and holding device that is flexible in its radial dimension such that it can be collapsed into a collapsed condition when in said tube and will open out within said blood vessel when it emerges from the tube,  
said filtering and holding device including coupling mechanisms, accessible through the endovenous route, that will enable the filtering and holding device to be seized and withdrawn percutaneously from the blood vessel.
2. The invention as set forth in claim 1 wherein said coupling mechanisms includes an element at each end of the filtering and holding device and each element of the coupling mechanisms is independently accessible percutaneously through an endovenous route.
3. The invention as set forth in claim 1 or 2 wherein said medical filter includes a recovery device that can be inserted percutaneously and threaded through an endovenous route such that its distal end is located at said filtering and holding device, and  
coupling mechanism carried by said recovery device at its distal end, said coupling mechanism carried by said recovery device being complementary to said coupling mechanism of said filtering and holding device such that said filtering and holding device can be seized by said recovery device.
4. The invention as set forth in claims 1 or 2 wherein said coupling mechanisms on the filtering and holding device are made of radiopaque material to assist in the procedure of securing the coupling mechanisms.

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5. The invention as set forth in claim 3 wherein said medical filter includes a recovery tube having an open distal end dimensioned to receive the collapsed filtering and holding device,

5 said recovery tube adapted to be inserted percutaneously into the patient and threaded over an endovenous route such that its open distal end is adjacent the filtering and holding device so that the filtering and holding device can be moved from its location within the blood vessel  
10 by said recovery device to a location within the distal end of said recovery tube.

6. A filter to be placed in the blood vessel of a patient for trapping clots, the filter being inserted  
15 percutaneously through a insertion tube and expelled from the insertion tube at a selected location in the blood stream, where it implants itself so as to prevent migration of the filter within blood vessel,

said filter including struts that open out from a collapsed condition when it is released from the insertion tube into the blood vessel of the patient at the desired position,

said struts functioning to filter out clots that are flowing through the blood vessel,

25 said struts having free ends that are forced into the side wall of the blood vessel as a result of a force attempting to move the filter axially of the blood vessel, said free ends functions as holding devices to anchor the filter at the desired position within the blood vessel,

30 said insertion tube including a pusher that is maneuverable from the proximal end of the insertion tube for expelling the filter out the distil end of the insertion tube.

35 7. The invention as set forth in claim 6 wherein said filter incudes a first and a second unit that are spaced from each other along the filter's longitudinal axis,

each of said units including a central hub into which a plurality of spurs are anchored such that their free ends radiate outwardly therefrom at an acute angle to said longitudinal axis in the direction toward the other of said units causing the free ends to engage the inner wall of said blood vessel,

said first and second units being interconnected by a compression spring extending along said longitudinal axis, said compression spring exerting a force on said units causing the free ends of the spurs to grip the inner wall of the blood vessel and hold the filter in its desired position.

8. A filter, having a longitudinal axis, to be placed in the blood vessel of a patient for trapping clots,

said filter including struts that open out from a collapsed condition when it is released into the blood vessel of the patient at the desired position,

said struts functioning to filter out clots that are flowing through the blood vessel and as holding devices to anchor the filter at the desired position within the blood vessel,

said filter including first and second units that are spaced from each other along the filter's longitudinal axis,

each of said units including a central hub into which a plurality of spurs are anchored such that their free ends radiate outwardly therefrom at an acute angle to said longitudinal axis in the direction toward the other of said units such that the free ends to said spurs engage the inner wall of said blood vessel,

said first and second units being interconnected by an elongated compression spring extending along said longitudinal axis, each end of said compression spring being connected to the central hub of one of said units, said compression spring exerting a force on said units causing the free ends of the spurs to grip the inner wall of the blood vessel and thus anchor the filter in its desired position.



9. The invention as set forth in claim 8, wherein each unit of said filter includes a core wire, one end of each core wire is anchored in the units central hub and extends from its anchor within the center of said compression spring toward the other unit, said core wires terminating in free ends short of said other unit.

10. The invention as set forth in claims 8 or 9 wherein said filter includes a coupling mechanism at each of its ends, each of said coupling mechanisms being accessible percutaneously through the blood vessel in which the filter is implanted.

11. A method of recovering a filter, of the type that extends along the longitudinal axis of a blood vessel and includes coupling mechanisms at each of its ends, that has been implanted in the vascular system of a patient, comprising the steps of:

(a) percutaneously insert a recovery tube into a vessel of the patients vascular system that leads to the implanted filter;

(b) advance the recovery tube through the patients vascular system to the point where the distal end of the recovery tube is in the vicinity of a first end of the implanted filter;

(c) percutaneously insert a second tube into a vessel of the patients vascular system that leads to a second end of the implanted filter;

(d) advance the second tube through the patients vascular system to the point where the distal end of the second tube is in the vicinity of the second end of the implanted filter;

(e) provide a coupling mechanism, that is complementary to the coupling mechanism on the filter, on one end of a first elongated member;

(f) advance the first elongated member through the recovery tube until the complementary coupling mechanisms on

the first end of the filter and on the distal end of the first elongated member are adjacent;

- 5 (g) manipulate the first elongated member from its proximal end to cause the adjacent coupling mechanism on the first end of the filter and the distal end of the first elongated member to become attached;
- (h) provide a coupling mechanism, that is complementary to the coupling mechanisms on the filter, on one end of a second elongated member;
- 10 (i) advance the second elongated member through the second tube until the complementary coupling mechanisms on the second end of the filter and on the distal end of the second elongated member are adjacent;
- (j) manipulate the second elongated member from its proximal end to cause the adjacent coupling mechanisms on the second end of the filter and the distal end of the second elongated member to become attached;
- 15 (k) apply and maintain a pressure in the proximal direction on the first and second elongated members;
- 20 (l) advance the second tube toward the filter such that it moves relative to the second elongated member and over the second end of the filter such that a portion of the filter is collapsed and contained within the second tube;
- (m) advance the recovery tube toward the filter such that it moves relative to the first elongated member and over the first end of the filter and the distal end of the second tube such that the entire filter is contained within the recovery tube;
- 25 (n) release the coupling mechanisms between the second end of the filter and the distal end of the second elongated member;
- 30 (o) withdraw the second tube and the second elongated member from the patient; and
- (p) withdraw the recovery tube containing the entire filter and the first elongated member from the patient.
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12. The method as set forth in claim 11 in which the filter is further of the type that has first and second units that are spaced longitudinally and connected by a spring and wherein step (k) causes the first and second units to expand the spring and moves the first and second units longitudinally relative to each other such that each unit moves relative to location in the blood vessel where it has been implanted.

13. The method as set forth in claims 11 or 12 wherein step (e) includes the following sub steps:

- (1) doubling a first cord over upon itself so that the cord has a loop at one end;
- (2) advancing the first cord, loop end first, through the first elongated member from the proximal to the distal end, until the loop exits the first elongated member at the distal end and functions as the coupling mechanism on one end of the first elongated member,
- (3) doubling a second cord over upon itself so that the cord has a loop at one end;
- (4) advancing the second cord, loop end first, through the second elongated member from the proximal to the distal end, until the loop exits the second elongated member at its distal end and functions as the coupling mechanism on one end of the second elongated member.

14. The method as set forth in claims 12 wherein step (n) includes the following sub steps:

- (1) release one end of the cord that exits the proximal end of the second elongated member;
- (2) pull on the other end of the cord that exits the proximal end of the second elongated member until the released end of the cord is pulled into the second elongated member, thus releasing the coupling mechanisms.

15. The method as set forth in claims 12 or 14 in which the coupling mechanisms provided on the filter and in steps (e) and (h) are made of radiopaque type material that can be

seen on a fluoroscope to thus aid in completing the coupling process.

16. A method of constructing a filter comprising the steps of:
- (a) providing a tube having open ends;
  - (b) inserting an end of a coupling mechanism into one of the open ends of said tube;
  - (c) inserting the ends of a plurality of outwardly diverging spurs into the other open end of said tube;
  - (d) inserting an end of a core wire into said other open end of said tube;
  - (e) filling all remaining space in the tube between its open ends with a bonding material that will harden to secure the coupling mechanism, plurality of spurs and core wire in the tube.

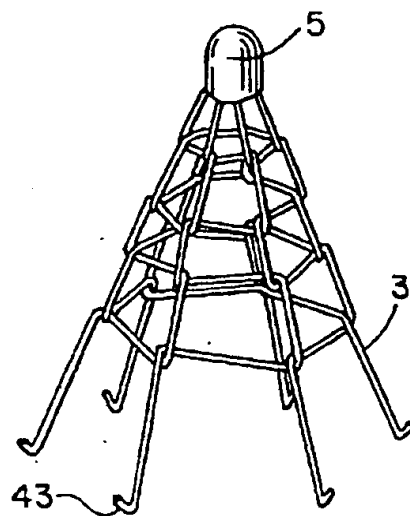
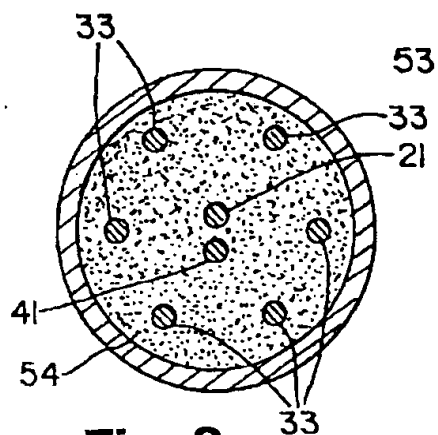
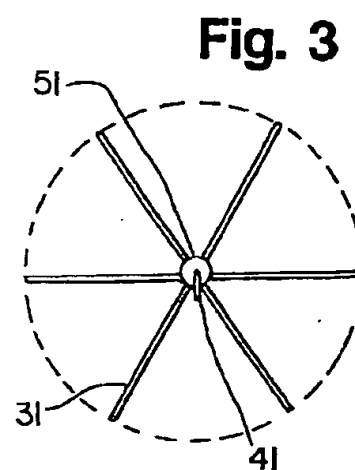
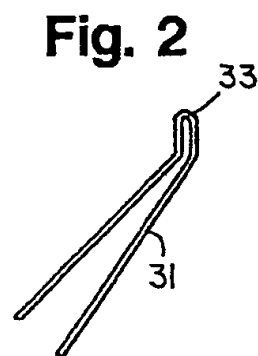
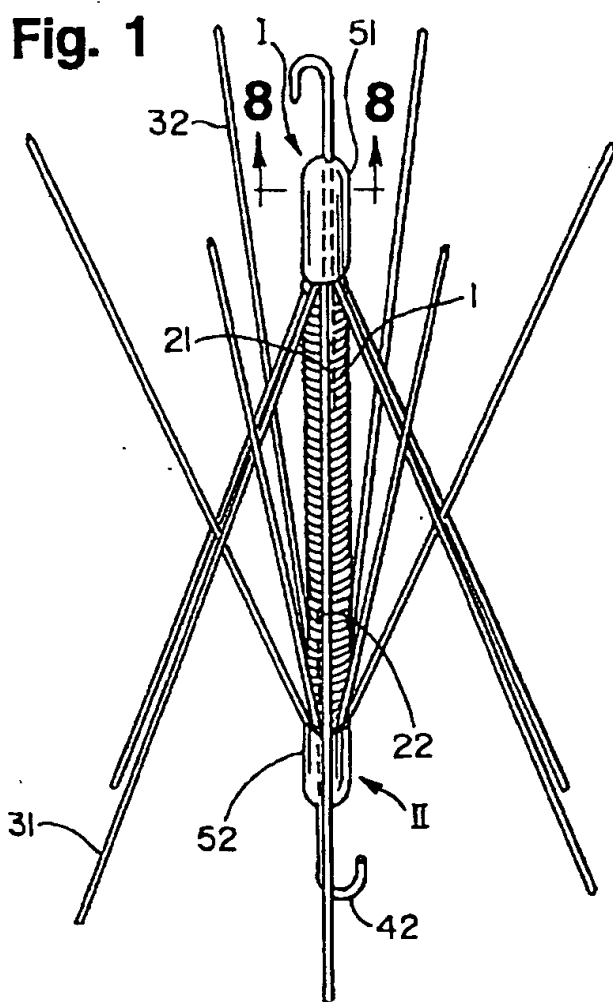
17. A method of constructing a filter of the type recited in claim 16 including the additional steps of:
- (f) providing a second tube having open ends;
  - (g) inserting an end of a coupling mechanism into one of the open ends of said second tube;
  - (h) inserting the ends of a plurality of outwardly diverging spurs into the other open end of said second tube;
  - (i) inserting an end of a core wire into said other open end of said second tube;
  - (j) connecting one end of a compression spring to said other end of said tube;
  - (k) connect the other end of said compression spring to said other end of said second tube; and
  - (l) filling all remaining space in said second tube between its open ends with a bonding material that will harden to secure the coupling mechanism, plurality of spurs and core wire in the tube.

18. A method of constructing a filter of the type recited in claim 16 in which the diverging spurs have free

ends extending from said tube that lie along the surface of a cone that has its apex within said tube.

19. A method of constructing a filter of the type recited in claim 17 in which the diverging spurs that have been bonded into said tube and said second tube have free ends extending from said tube and said second tube that lie along the surfaces of cones that have their apices within said tube and said second tube.

20. A method of constructing a filter of the type recited in claim 19 in which the diverging spurs extending from said tube cross the diverging spurs extending from said second tube.



**Fig. 9**  
**PRIOR ART**

SUBSTITUTE SHEET



## INTERNATIONAL SEARCH REPORT

PCT/US92/11311

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(5) : A61B 17/00 US CL : 606/200 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : 606/108,195,198,200; 128/898 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A, 4,425,908 (SIMON) 17 JANUARY 1984 See entire document	1-6
X	US,A, 4,832,055 (PALESTRANT) 23 MAY 1989 See entire document	1-6
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be part of particular relevance "E" earlier document published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "A" document member of the same patent family		
Date of the actual completion of the international search 19 MARCH 1993		Date of mailing of the international search report 03 MAY 1993
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE		Authorized officer <i>Andre Robinson</i> WILLIAM LEWIS Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet)(July 1992)\*